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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,548	01/16/2002	John Austin Burns	38-21(51450)	7713

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,548

Applicant(s)

BURNS ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12,14 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,14 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/17/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 3/1/2004 has been entered.

Claims 1-7, 9-12, 14, 18-20 are pending.

Claims 8, 13, 15-17, and 21-23 have been canceled.
2. Claims 1-7, 9-12, 14, 18-20 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson et al (1977, Journal of Horticultural Science 52:169-171).

The claims are drawn to a method for regenerating a plant comprising culturing zygotic embryo comprising a shoot meristem or primordia on a medium comprising an apical dominance inhibitor dikegulac, methyl laurate or octadecyl-polyethoxyethanol and rooting the cultured explant to produce a plant. The claims are further limited to include an auxin wherein the auxin is IAA or the medium also includes a cytokinin, and wherein the plant is a dicotyledonous plant.

Jackson et al teach a method of regenerating a taro plant comprising culturing taro seeds on a medium containing IAA, kinetin, and the apical dominance inhibitor octadecyl-polyethoxyethanol (OPE) (page 169, 'Culture medium' paragraph), wherein cultured seeds produced five to ten shoot tips (page 170, 3rd paragraph and abstract). Jackson et al also disclose

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that regenerated plantlets were transferred to soil (page 170, 4th paragraph), and as such, Jackson et al anticipate the claimed invention.

Obviousness

6. Claims 1-7, 9-12, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al (1977, Journal of Horticultural Science 52:169-171) as applied to claims 1-3, and 11 above, and further in view of George (1993, Plant Propagation by Tissue Culture, Exegetics Ltd, Great Britain, page 469, listed in IDS).

The claims are drawn to a method for regenerating a plant comprising culturing zygotic embryo comprising a shoot meristem or primordia on a medium comprising an apical dominance inhibitor dikegulac, methyl laurate or octadecyl-polyethoxyethanol (OPE) or wherein the apical dominance inhibitor is dikegulac at a concentration from about 5 to about 5000 mg/L or about 10 to about 1000 mg/L, or wherein the medium contains any of the salt mixtures as listed in claim 18, and rooting the cultured explant to produce a plant. The claims are further limited to include an auxin wherein the auxin is IAA and the medium also includes the cytokinin BA or ZR, and wherein the plant is any dicotyledonous plant, a cotton plant or a soybean plant.

The teachings of Jackson et al have been discussed above.

Jackson et al do not teach the apical dominance inhibitor dikegulac, wherein the dikegulac is present at a concentration from about 5 to about 5000 mg/L or about 10 to about 1000 mg/L, a cotton or soybean plant regenerated by said method, or Jackson et al do not teach any of the salt mixtures listed in claim 18.

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George teaches the apical dominance inhibitors dikegulac, methyl laurate or octadecyl-polyethoxyethanol that are used in culture media to increase the number of shoot meristems that are produced from a given explant. George also teaches using 500 to 1000 mg/l dikegulac.

Given the recognition of those of ordinary skill in the art of the value of regenerating plants using tissue culture techniques which incorporate the apical dominance inhibitor octadecyl-polyethoxyethanol that induces multiple shoots to be produced from an embryo explant as taught by Jackson et al, and given the value of adding the apical dominance inhibitor dikegulac, to culture media to increase the number of shoot meristems that are regenerated from tissue explants as taught by George (See page 469, left column, last sentence), it would have been obvious to substitute dikegulac for octadecyl-polyethoxyethanol in the method of Jackson et al so as to increase the number of shoot meristems that are produced from a single explant, given the lack of evidence to the contrary. In addition, a concentration of dikegulac between about 5 and about 5000 mg/L, which is such a wide range that one skilled in the art would routinely use at least one concentration within the range as claimed and the use of any of the salt mixtures as listed in claim 18 would be incorporated in optimization of process parameters, with a reasonable expectation of success. Using soybean or cotton would constitute a personal design choice given the value of regenerating an agronomically important plant such as cotton or soybean, and given the lack of disclosure by Applicant foretelling unexpected results for regenerating soybean versus cotton, given Applicants' disclosure of cotton regeneration.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

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Applicant's arguments filed 3/1/2004 have been fully considered but they are not persuasive.

Applicants contend that George does not teach, disclose or suggest the use of an apical dominance inhibitor in tissue culture where the explant is an embryo in view of the literature that used an apical dominance inhibitor on growing plant tissue (page 6, 2nd full paragraph).

Applicants purport that embryos have a single meristem and there was no suggestion that use of an apical dominance inhibitor could cause the embryo to form multiple adventitious meristems and from there produce multiple shoots (*ibid*).

The Office contends that George teaches that dikegulac and octadecyl-polyethoxyethanol (OPE) are apical dominance inhibitors because they are disclosed in the section entitled "compounds which can arrest apical growth" and George further discloses that dikegulac was used in culture to increase the number of shoots that developed from cultured shoots of sweet cherries (page 469, left column, last sentence). The Office contends that the George reference is used as a secondary reference teaching dikegulac, which is combined with Jackson et al who teaches embryos can be induced to form multiple shoots when cultured on a medium comprising OPE, another apical dominance inhibitor, also taught by George immediately following the disclosure of dikegulac.

7. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al (1977, Journal of Horticultural Science 52:169-171), and further in view of Umbeck (April 1991, U.S. Patent 5,004,863).

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The claims are drawn to a method for regenerating a transgenic plant comprising culturing an embryo on a medium comprising an apical dominance inhibitor dikegulac, methyl laurate or octadecyl-polyethoxyethanol and rooting the cultured explant to produce a plant. The claims are drawn to transforming said embryo before or after the introduction of a recombinant DNA in the embryo.

The teachings of Jackson et al have been discussed above.

Jackson et al do not teach transforming an embryo.

Umbeck teaches a method of transforming and regenerating cotton plants comprising growing cotton plants in vitro, culturing hypocotyl explants on medium, inoculating explants with *Agrobacterium*, selecting transformed callus and regenerating whole plant (columns 7-9, Example 1).

Given the recognition of those of ordinary skill in the art of the value of regenerating plants using tissue culture techniques which incorporate the apical dominance inhibitor octadecyl-polyethoxyethanol that induces multiple shoots to be produced from an embryo explant as taught by Jackson et al, and given the method of transforming cotton explants as taught by Umbeck, it would have been obvious to produce transgenic plants by combining the method of Jackson et al to regenerate multiple plants from a single explant with the method of transforming a plant using *Agrobacterium* of Umbeck. One of ordinary skill in the art would not expect unexpected results when the explant was transformed, either before or after treatment with octadecyl-polyethoxyethanol. The decision to transform the explant either before or after treatment with octadecyl-polyethoxyethanol would be an experimental design choice that lacks

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any patentable weight. In addition, absent evidence to the contrary, there would be no unexpected result transforming either an embryo or a hypocotyl.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant's arguments filed 3/1/2004 have been fully considered but they are not persuasive.

Applicants contend that Umbeck does not suggest, disclose or teach the use of an apical dominance inhibitor in combination therewith nor the use of embryos as the desired explant (page 7, 1st paragraph).

The Office contends that in the present rejection, the teachings of Umbeck are used for its teachings of *Agrobacterium* mediated transformation of plant tissue. This reference is combined with Jackson et al who teach embryo culture using an apical dominance inhibitor to induce multiple shoots from an embryo. Applicants arguments are moot, based on the above rejection.

8. No claims are allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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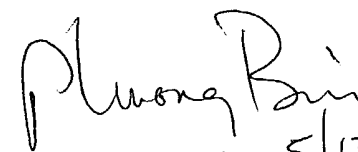
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
May 12, 2004


PHUONG T. BUI
PRIMARY EXAMINER
5/13/04